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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,522	04/06/2005	Norbert Heske	289-PDD-03-08 US	6406
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C. R. Bard, Inc. Bard Peripheral Vascular, Inc. 1415 W. 3rd Street P.O. Box 1740 Tempe, AZ 85280-1740				
EXAMINER				
LLOYD, EMILY M				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,522

Applicant(s)

HESKE ET AL.

Examiner

EMILY M. LLOYD

Art Unit

3736

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 Jun 2004, 9 May 2008 and 29 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 96-143 is/are pending in the application.
- 4a) Of the above claim(s) 97-110 and 116-143 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 96 and 111-115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :20040629, 20041005, 20041230, 20051011, 20080509, 20080925, 20091124.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group E in the reply filed on 29 May 2009 is acknowledged. The traversal is on the ground(s) that Applicant argues that US Patent 4989614 (Dejter) does not teach a cutting sheath and the tension slide being brought into a cocked position against the action of a spring by the power source. This is not found persuasive because the sheath of Dejter can be considered a cutting sheath as it covers a cutting element (a cutting sheath can be a sheath for cutting tissue or a sheath for covering a cutter; Dejter teach the latter) and as Dejter teaches that the tension slide (syringe carriage 40, part of "entire carriage assembly" in Column 13 lines 58-63) is brought into a cocked position against the action of a spring (spring 61) by the power source (battery 92 controlling solenoid 90) (see entire document, including Column 13 line 54-Column 14 line 6). The Examiner notes that "to cock" is defined as "To set (a device, such as a camera shutter) in a position ready for use"; as the solenoid sets the tension slide/syringe carriage against the springs in a position so that it is ready for use when released by the solenoid, the tension slide is brought into a cocked position against the action of a spring by the power source.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 97-110 and 116-143 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable

generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 29 May 2009.

Information Disclosure Statement

3. The information disclosure statements filed 11 October 2005 and 24 November 2009 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.
4. The information disclosure statements filed 29 June 2004 and 11 October 2005 fail to comply with 37 CFR 1.98(a)(3) because they do not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because: reference characters "21", "39" and "71" have both been used to designate "sample removal chamber"; reference characters "42" and "46" have both been used to designate "extension"; and reference characters "81" and "101" have both been used to

designate "guide roller". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because: reference character "21" has been used to designate both "DC gear motor" and "sample removal chamber"; reference character "39" has been used to designate both "not used" and "sample removal chamber"; reference character "46" has been used to designate both "cover" and "extension"; and reference character "101" has been used to designate both "flanks of the guide roller left" and "guide roller". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

7. The drawings are objected to because the figure labels and component numbers are difficult to read; Figures 3-5 should have sections B-B and C-C, as described on page 9 of the specification and in consideration of Figure 1 defining section A-A that is illustrated in Figure 3; and Figure 11e has the word "Schnitt" in it with no corresponding explanation in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 99, 126, and T. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

9. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 127. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

10. The disclosure is objected to because of the following informalities: [0007] line 2 the word "the" should be inserted between "between" and "hollow"; [0016] line 3 the word "depth" should be "depths"; [0019] line 11 the word "needed" should be "needle"; [0022] line 7 the word "the" should be inserted between "between" and "coaxial"; [0033] lines 1-2 should be revised for clarity; [0035] line 1 should reference Figure 9A instead of Figure 9; [0036] line 1 should reference Figure 9B instead of Figure 9A; [0063] line 3, [0072] line 3, [0080] line 2, and [0108] line 4 "Figure" should be "Figures"; [0070] lines 4-5 the word "the" should be inserted between "for" and "cutting"; [0071] line 5 the word "is" should be inserted between "114" and "arranged"; [0074] lines 8-9 should be revised for clarity; [0080] line 3 should be revised for clarity; [0085] line 4 "plane" should be "planar"; [0088] line 1 the ":" should be a period; [0092] line 3 the word "and" should be inserted between "green," and "the"; [0097] line 3 Figure 14c should be referenced instead of Figure 11c; [0101] line 11 "open" should be "opened"; [0103] lines 14-15 component 120 is not labeled in Figure 15 as described; [0104] lines 13-14 should be revised for clarity; [0105] line 2 "Figure 16, 17" should instead say "Figures 16 and 17"; [0105] line 11 the word "a" should be inserted between the words "in" and "sterile"; and page 35 the number 43 should be inserted into the table with the corresponding part name of "lower sliding surface".

Appropriate correction is required.

Claim Interpretation - 35 USC § 112 Sixth Paragraph

11. The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

12. Further, MPEP 2181 provides the following 3-prong test for determining if 35

USC 112 6th paragraph is invoked:

A claim limitation will be presumed to invoke 35 U.S.C.112, sixth paragraph, if it meets the following 3-prong analysis:

(A) the claim limitations must use the phrase "means for" or "step for;"

(B) the "means for" or "step for" must be modified by functional language; and

(C) the phrase "means for" or "step for" must not be modified by sufficient structure, material, or acts for achieving the specified function.

13. The Examiner notes that no limitations meet the 3-prong analysis and thus no limitations are interpreted as invoking 35 USC 112 6th paragraph. The Examiner notes that "means of a DC motor" (claim 111) is not modified by functional language and provides sufficient structure.

14. The Examiner further notes that MPEP 2181 states:

With respect to the first prong of this analysis, a claim element that does not include the phrase "means for" or "step for" will not be considered to invoke 35 U.S.C. 112, sixth paragraph. If an applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant must either: (A) amend the claim to include the phrase "means for" or "step for" in accordance with these guidelines; or (B) show that even though the phrase "means for" or "step for" is not used, the claim limitation is written as a function to be performed and does not recite sufficient structure, material, or acts which would preclude application of 35 U.S.C. 112, sixth paragraph. See *Watts v. XL Systems, Inc.*, 232 F.3d 877, 56 USPQ2d 1836 (Fed. Cir. 2000) (Claim limitations were held not to invoke 35 U.S.C. 112, sixth paragraph, because the absence of the term "means" raised the presumption that the limitations were not in means-plus-function form and the applicant did not rebut that presumption.); see also *Masco Corp. v. United States*, 303 F.3d 1316, 1327, 64 USPQ2d 1182, 1189 (Fed. Cir. 2002) ("[W]here a method claim does not contain the term 'step[s] for,' a limitation of

that claim cannot be construed as a step-plus-function limitation without a showing that the limitation contains no act.”).

15. As such, limitations that do not explicitly state “means for” have been considered to not invoke 35 USC 112 6th paragraph.

Claim Rejections - 35 USC § 112

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 111-115 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding claim 111, Applicant’s now-cancelled claim 63, filed as a new claim on the same day that Applicant filed their US application under 35 USC 371, claimed a “single-stage secondary transmission” but no description of this was provided in the specification. Claims 112-115 are rejected as ultimately depending on claim 111.

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 111-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 111, it is unclear what a "single-stage secondary transmission" defines. It is unclear if this is a transmission with only one direction, that only operates during one stage of a process, that operates when a primary transmission is not moving, that operates when a primary transmission is unable to move, that is smaller than a primary transmission, and/or another definition. Claims 112-115 are rejected as ultimately depending on claim 111.

Regarding claims 114 and 115, it is unclear if "a spindle actuator" is the same spindle actuator as claim 111 or a different spindle actuator; if they are different, it is unclear which spindle actuator is referred to in claim 115.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claim 96 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4989614 (Dejter).

Dejter discloses a biopsy device for taking tissue samples (Figures 13-16), comprising: a housing (casing 1 Figure 13) containing an electric power source (battery 92 Column 12 lines 9-11) and a tension slide (syringe carriage 40 Figure 13) connected to the power source, wherein the tension slide is brought into a cocked position against the action of a spring (spring 61 Figure 16) by the power source (see entire document,

including Column 13 line 54–Column 14 line 6); a removable element (Column 11 lines 5-7) configured for insertion into the housing, comprising: a biopsy needle unit, comprising a hollow biopsy needle (needle 2 Figure 13), having a sample removal chamber (sample storage portion 20 of needle 2 Figure 13), and a cutting sheath (sheath 6 Figure 13), wherein the biopsy needle unit is arranged on the tension slide (syringe carriage 40 Figure 13); a vacuum pressure-generating device (syringe carriage 40 and plunger support bracket 45 moving plunger 5 with respect to syringe 4, Figure 13); and a connection element connecting the biopsy needle unit and the vacuum pressure-generating device (luer-lock connections 18, 31 Figure 13 and Column 10 lines 16-18); and a control panel attached to the housing (electronic control circuit 109 Figure 13).

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 96 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45, 49, 91 and 94 of copending Application No. 11/680882 in view of Dejter. Application 11/680882 teaches a biopsy device for taking tissue samples (claim 45), comprising: a tension slide (needle-shooting mechanism claim 45), wherein the tension slide is brought into a cocked position against the action of a spring (claim 49); a removable element configured for insertion into the biopsy device, comprising: a biopsy needle unit, comprising a hollow biopsy needle, having a sample removal chamber, and a cutting sheath (claim 45), wherein the biopsy needle unit is arranged on the tension slide (claim 45); a vacuum pressure-generating device (claims 91 and 94); and a connection element connecting the biopsy

needle unit and the vacuum pressure-generating device (inherent per claim 91 to operate). Application 11/680882 does not expressly claim a housing containing an electric power source and a control panel attached to the housing. Dejter teaches a housing (casing 1 Figure 13) containing an electric power source (battery 92 Column 12 lines 9-11) and a control panel attached to the housing (electronic control circuit 109 Figure 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the housing, electrical power source and control panel as taught by Dejter with the claimed invention of Application 11/680882 to provide for protecting the mechanisms of the application with a housing and to provide for automating the biopsy device.

This is a provisional obviousness-type double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
Art Unit 3736

/EML/

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736